PATENT COOPERATION TREATY

From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

Fax-no.: 2123 - 9922

PCT

To:

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NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	02.02.2005
Applicant's or agent's file reference	IMPORTANT NOTIFICATION
.....	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP 03/07741	16.07.2003	02.08.2002

Applicant
RATIOPHARM GMBH et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the International preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Oberhauser, A Tel. +49 89 2399-8139

Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP 03/07741	International filing date *(day/month/year)* 16.07.2003	Priority date *(day/month/year)* 02.08.2002
International Patent Classification (IPC) or both national classification and IPC A61K9/50		
Applicant RATIOPHARM GMBH et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
22.01.2004	02.02.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Vermeulen, S Telephone No. +49 89 2399-7520

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/07741

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-14 as originally filed

Claims, Numbers

1-20 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3-10,13-15,20
	No:	Claims	1,2,11,12,16-19
Inventive step (IS)	Yes:	Claims	3-10,20
	No:	Claims	1,2,11-19
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

NOVELTY - INVENTIVE STEP

Reference is made to the following document/s/:

D1: US-A-6 096 340 (CHIH-MING CHEN; ET AL.) 1 August 2000
D2: EP-A-1 010 423 (LICONSA) 21 June 2000
D3: EP-A-1 108 425 (LABORATORIOS MEDINFAR) 20 June 2001

Claims 1, 2, 11-19

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claims 1, 16 and 18 is not new in the sense of Article 33(2) PCT in view of prior art disclosures which can be taken from D1-D3.

The cited documents D1, D2 and D3 disclose inert cores coated with a drug layer and an enteric layer. The drug layer comprises a benzimidazole compound together with excipients including a filler such as microcrystalline cellulose. Document D3 also provides an intermediate layer between the drug layer and enteric layer. Accordingly, the cited documents anticipate the subject-matter of claims 1 and 16. Also claim 18 is considered not to be novel, since the use of microcrystalline cellulose in general as an excipient in benzimidazole coatings is disclosed in D1-D3. According to the definition of claim 18 a stabilizing effect is inherent to any type of microcrystalline cellulose. Hence, a stabilizing effect is also considered implicit for the microcrystalline cellulose used in D1-D3, thus anticipating the subject-matter of claim 18.

In view of the state of the art disclosed in D1-D3, also the dependent claims 2, 11-15, 17 and 19 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, would render the claimed subject-matter novel and/or inventive (Art.33(2)-(3) PCT). D1-D3 deal with benzimidazoles and disclose specific compounds such as omeprazole, lansoprazole, pantoprazole, etc. The inclusion of an intermediate layer separating the drug layer and enteric layer is a common practice, illustrated e.g. by D3. Also the coating method, comprising spraying of an aqueous drug suspension, is suggested by D1-D3. Furthermore, none of the specific embodiments appears to bring a solution to the problem underlying the present application.

Claims 3-10 and 20

According to the present application (cf. description page 3, last paragraph) stabilization of benzimidazoles occurs through interaction with the extensive surfaces of microcrystalline cellulose. As a consequence, the particle size and distribution appears to be an essential feature in the definition of the invention. The subject-matter of claims 3-10 defines specific particle size/distribution and density of the microcrystalline cellulose, which are not disclosed by any of the prior art documents. Accordingly, the subject-matter of claims 3-10 is novel (Art. 33(2) PCT). In addition, the subject-matter of claims 3-10 is also considered to involve an inventive step (Art. 33(3) PCT), since none of the prior art documents suggests to include microcrystalline cellulose of a defined particle size in a coating comprising a benzimidazole compound, in order to provide enhanced stability of said benzimidazole compound. Claim 20 refers to claims 3-10 and as such also meets the requirements of the PCT with respect to novelty and inventive step.

INDUSTRIAL APPLICABILITY

The subject-matter of claims 1-20 is considered to be industrially applicable and accordingly meets the requirements of Art.33(4) PCT.